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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,574	02/09/2004	Frank V. Barone JR.	4806-7	1468

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EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,574

Applicant(s)

BARONE ET AL.

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/6/05, 6/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 are pending in the application.

Election/Restrictions

Applicant's election of Group I, claims 1-11 in the reply filed on 6/9/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 12, directed toward the non-elected invention, was subsequently cancelled in the amendment filed 6/9/05.

Claims 1-11 were examined on the merits.

Information Disclosure Statement

The reference submitted to Finnin was not considered because the Office's copy is illegible. Applicant is asked to submit a readable copy; thereupon, the Examiner will consider this reference.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-11 recite 'extract'. It is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially *enormous* number of extracts.

Although Applicant has disclosed certain solvents which could potentially be used to extract muira puama, catuaba and maca, this is actually a very few number in comparison to the enormous, potentially millions of types of extracts which could be obtained from cucumber. The reason for this large amount of permutations is because extraction techniques are often coupled in order to obtain a product; for example

1) a water extraction followed by an alcoholic extraction: the product obtained is an extract.

2) a supercritical extraction (CO_2) followed by an alcoholic and then a non-polar solvent extraction (e.g., chloroform): the product is an extract.

3) a benzene extraction followed by a water extraction and chromatographic separation: the product is an extract.

4) a water/chloroform extraction (e.g., in a separatory funnel), followed by collection of the water layer, chromatographic separation and crystallization of an isolate: the product is an extract.

5) squeezing the plant and/or fruit of the plant to obtain a juice: the product is an extract.

6) dipping the plant in an organic solvent to remove the waxy layer: the product is an extract.

Therefore, it is deemed that Applicant was not in possession of a reasonable number of potential extracts of cucumber and therefore the rejection is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by 'Alternative Medicine Network (AMN): Women's Health' WWW site (archived to 1/28/2003).

AMN disclosed a topically applied cream for sexual fitness named 'Satisfaction' which contained L-arginine and Methyl nicotinate, *inter alia* (see pages 1 and 2 of print-out, especially page 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over 'Alternative Medicine Network (AMN): Women's Health' WWW site (archived to 1/28/2003) in view of Denton et al. (US 2003/0077296 A1) in view of Duckett et al. (US 6,340,480 B1) in view of Harbeck (US 2002/0817165 A1) in view of Neumayr, M (DE 04007975, English Abstract) in view of Whitely, J. (2000) and in view of Kelly (US 5,208,031).

The teachings of AMN (2003) were discussed *supra*. AMN did not expressly disclose the incorporation of catubaa extract, muira puama extract, maca, saw palmetto, zinc or yohimbe.

Denton et al. (US 2003/0077296 A1) disclosed a topical cream for enhancing sexual response which included maca (*Lepidium meyenii*) extract, L-arginine, aloe, water and propylene glycol, *inter alia* and also specifically suggested the incorporation of catuaba extract since catuaba was a known aphrodisiac, (see claim 7 and [0004] for example).

Duckett et al. (US 6,340,480 B1) disclosed a topical ointment comprising L-arginine and saw palmetto (see claims 1 and 6 for example).

Harbeck (US 2002/0817165 A1) taught a topical composition for improving sexual arousal which comprised yohimbe in a cream base (see claims 11 and 12 for example).

Neumayr, M (DE 04007975, English Abstract) disclosed an aphrodisiac composition comprising *Muira puama* (English Abstract). It is clear that the composition is topical, in that Neumayr states 'are effective 30-60 min. after application'.

Whitely, J. (2000) reporting for the Las Vegas Review, indicated that the product 'Passion Booster' included ingredients such as nettle-root extract, muira puam extract and arginine (see p. 3 of ProQuest direct print-out).

Kelly (US 5,208,031) disclosed a sexual lubricant comprising zinc, an agent which inhibits replication of the herpes virus (see Abstract for example).

Reyes (US 6,803,060 B2) disclosed a lotion applied topically to 'boost libido' comprising vitamin E and L-arginine *inter alia* (see for example, col. 7, lines 20-27).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for topical enhancement of sexual response. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the

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art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art do not teach all the various permutations of concentration ranges as claimed in claims 1-11, it would be conventional and within the skill of the art to identify the optional concentrations of a given component because the selection of appropriate concentration of components to increase sexual response would have been conventional and within the skill in the art at the time the invention was made.

Although the references did not specifically teach that nettle was administered topically, it is deemed that the ordinary artisan would have been motivated to apply nettle topically and directly to the site in order to facilitate arousal because it is clear from the prior art that nettle was known in the art for treating libido. Further, Vitamin E is a well known topical

Although zinc was not used specifically for increasing sexual response, one of ordinary skill in the art would have been motivated to add zinc to the composition in order to impart herpes prevention to the composition. It is clear from the prior art that

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the addition of zinc to topical lubricants was conventional in the art. Therefore the ordinary artisan would have had a good expectation that zinc, when combined with any composition applied to the penis or vagina in order to aid in sexual arousal, would have offered the additional benefit of herpes prevention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Hence, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

8/17/05

A handwritten signature in cursive script, reading "Patricia Leith", positioned below the printed name and title.